

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF LOUISIANA, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW ORK, CITY OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN	:	CIVIL ACTION
ex rel. PANZEY BELGIUM HARRIS, and SMSPF, LLC	:	
	:	
v.	:	
	:	
EMD SERONO, INC., PFIZER, INC. QUINTILES IMS HOLDINGS, INC. and RXC ACQUISITION COMPANY, d/b/a RXCROSSROADS	:	
	:	NO. 16-5594

MEMORANDUM OPINION

Savage, J.

April 3, 2019

In this *qui tam* action brought under the False Claims Act, 31 U.S.C. §§ 3727-33, and various state laws, relators SMSPF, LLC and Panzey Belgium Harris bring claims against pharmaceutical companies, EMD Serono, Inc., and Pfizer, Inc., and marketing consultants and specialists, Quintiles IMS Holdings, Inc.,¹ and RXC Acquisition Company.

¹ Since the filing of this action, defendant Quintiles IMS Holdings merged and is currently known as IQVIA, Inc. See Second Am. Compl. (ECF No. 36).

They allege the defendants improperly engaged in “white coat marketing” and provided free nursing and reimbursement support services in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). The government, having completed its investigation and determining that the allegations lack merit, declined to intervene in the action. It now moves to dismiss all claims under 31 U.S.C. § 3730(c)(2)(A).²

Considering the parties’ submissions and after a hearing, we conclude that the government’s decision not to pursue this action is based on a legitimate governmental purpose and is not arbitrary. Therefore, we shall grant its motion and dismiss the action.

Factual Background

SMSPF, LLC is a limited liability shell company established by Venari Partners, LLC, doing business as National Health Care Analysis Group, a limited liability corporation comprised of other similar entities.³ These companies are relators in multiple *qui tam* actions making substantially the same allegations in eight judicial districts.⁴

² All named state plaintiffs, except New Jersey which takes no position on the motion, consent to the United States’ motion to dismiss so long as it is without prejudice to the states. Mot. to Dismiss at n.1 (ECF No. 23).

³ Mot. to Dismiss at 2.

⁴ See Mot. to Dismiss at 2-3 and Reply at 1 (ECF No. 63), listing twelve other *qui tam* actions against dozens of defendants. These cases are: *United States ex rel. SAPF, LLC, et al. v. Amgen, Inc., et al.*, No. 16-cv-5203 (E.D. Pa.); *United States ex rel. NHCA-TEV, LLC v. Teva Pharm., et al.*, No. 17-cv-2040 (E.D. Pa.); *United States ex rel. SMSF, LLC, et al. v. Biogen Inc., et al.*, No. 1:16-cv-11379 (D. Mass.); *United States ex rel. SCEF, LLC v. Astra Zeneca PLC, et al.*, No. 17-cv-1328 (W.D. Wash.); *United States ex rel. Miller, et al. v. AbbVie, Inc.*, No. 3:16-cv-2111 (N.D. Tex.); *United States ex rel. Carle, et al. v. Otsuka Holdings Co., et al.*, No. 17-cv-966 (N.D. Ill.); *United States ex rel. CIMZNHCA v. UCB, Inc., et al.*, No. 3:17-cv-00765 (S.D. Ill.); *United States ex rel. Health Choice Group, LLC v. Bayer Corp., et al.*, No. 5:17-cv-126 (E.D. Tex.); *United States ex rel. Health Choice All., LLC v. Eli Lilly & Co., et al.*, No. 5:17-cv-123 (E.D. Tex.); *United States ex rel. Health Choice Advocates, LLC v. Gilead, et al.*, No. 5:17-cv-121 (E.D. Tex.); and *United States ex rel. Doe and APBQR, LLC v. Sanofi-Aventis U.S. LLC, et al.*, No. 16-5107 (S.D.N.Y.). Four of these actions have been dismissed, and seven are pending.

SMSPF originally filed this action under seal on October 21, 2016.⁵ It amended the complaint to add Panzey Belgium Harris, a former Pfizer employee, as an individual co-relator on April 26, 2017.⁶ Relators filed a second amended complaint on December 28, 2018.⁷

The gravamen of the complaints are the same. Relators allege that the defendants, pharmaceutical companies and commercial outsourcing vendors, together engaged in “white coat marketing” and provided a variety of free services to induce doctors to prescribe the multiple sclerosis medication Rebif.⁸ They claim these actions violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b).

On June 27, 2018, after investigating the case for over 18 months, the government declined to intervene.⁹ We lifted the seal on August 30, 2018.¹⁰ The government now moves to dismiss this action pursuant to 31 U.S.C. § 3730(c)(2)(A).¹¹ It contends that the allegations lack merit, and continuing to monitor, investigate, and prosecute the case will be too costly and contrary to the public interest.

⁵ Compl. (ECF No. 1).

⁶ First Am. Compl. (ECF No. 4).

⁷ Second Am. Compl.

⁸ Second Am. Compl. ¶¶ 2-7.

⁹ Government Notice of Election to Decline Intervention (ECF No. 9).

¹⁰ Unsealing Or. (ECF No. 10).

¹¹ The government acknowledges it filed its motion prior to the filing of relators’ second amended complaint. Mot. to Dismiss at 8. The government states that it had spoken to relators’ counsel multiple times regarding its intent to file this motion and its perceived deficiencies in the case. The government also represents that “[h]aving had the opportunity to review substantially similar amendments in numerous other cases filed by [SMSPF’s parent company], [it] does not believe the newly-added details will change its analysis or request for dismissal.” *Id.*

Relators contend that the government has failed to demonstrate that its decision to dismiss has a rational relationship to a governmental interest. They argue that the decision to dismiss this action and the other similar actions is arbitrary, irrational, and not in the public interest.

Analysis

A private individual, known as a relator, can bring a *qui tam* action under the FCA on behalf of the United States. 31 U.S.C. § 3730(a), (b)(1); *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 411-12 (2005) (citing *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769-72 (2000)). Because a relator brings the action on behalf of the government, he must give the government notice of the action. The government may elect to intervene in the action then or later for good cause. *Graham Cty.*, 545 U.S. at 412; 31 U.S.C. § 3730(b)(2), (c)(3). If the government declines to intervene, the relator has the right to proceed with the prosecution of the case on behalf of the government. 31 U.S.C. § 3730(b)(4)(B). In that event, the relator determines the course of the action. *Id.* § 3037(c)(3).

Even if the government does not intervene, it retains its rights throughout the litigation. The relator cannot dismiss the action without the written consent of the Attorney General. The government may move to stay the action if it would interfere with the government's investigation or prosecution in another matter. It may intervene in the action "at a later date upon a showing of good cause." See *id.* § 3730(b)(1), (c)(3)-(4). In short, the government may exercise its rights whether it intervenes or not.

Section 3730(c)(2)(A) provides that "[t]he Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been

notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.”¹² The statute is silent as to the purpose and scope of the hearing. Nor does it provide any grounds for granting or denying dismissal.

Courts disagree on the standard for dismissing an action on the government’s motion over a relator’s objection. The Ninth and Tenth Circuits apply the “rational relationship” test which requires the government to justify its decision by showing that dismissal is related to a valid governmental purpose. *Sequoia*, 151 F.3d at 1145-47; *Ridenour*, 397 F.3d at 936 (quoting *Sequoia*, 151 F.3d at 1145). The District of Columbia Circuit holds that the government’s right to dismiss is unfettered. *Swift*, 318 F.3d at 252. The Third Circuit has not yet addressed the issue.

The Ninth Circuit, in *Sequoia*, established the “rational relationship” test. It held that dismissal of a *qui tam* action pursuant to § 3730(c)(2)(A) is appropriate only if the government has a valid governmental purpose, and dismissal is rationally related to accomplishing that legitimate governmental interest. *Sequoia*, 151 F.3d at 1145-47. If the government satisfies this test, “the burden switches to the relator to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal.” *Id.* at 1145. The *Sequoia*

¹² The government need not intervene in order to move to dismiss the action because it retains the right to dismiss it under § 3730(c)(2)(A). See *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1974 (2015). See also *Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 932 (10th Cir. 2005) (declining to construe the FCA as requiring intervention before moving to dismiss “because a plain reading of the statute does not require it, canons of statutory construction do not support such a result, and . . . such a reading would render the FCA constitutionally infirm.”); *Swift v. United States*, 318 F.3d 250, 251-52 (D.C. Cir. 2003), *cert. denied*, 539 U.S. 944 (2003) (finding intervention necessary “only if the government wishes to proceed with the action” and “[e]nding the case by dismissing it is not proceeding with the action”) (internal citations omitted); *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir.1998); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 753 n.10 (9th Cir. 1993) (citing *Juliano v. Fed. Asset Disposition Ass’n*, 736 F. Supp. 348 (D.D.C. 1990), *aff’d*, 959 F.2d 1101 (D.C. Cir. 1992)); *United States ex rel. Schweizer v. Oce N.V.*, 677 F.3d 1228, 1233 (D.C. Cir. 2012); *United States v. Everglades Coll., Inc.*, 855 F.3d 1279, 1286 (11th Cir. 2017).

court also held that “[a] hearing is appropriate ‘if the relator presents a colorable claim that the settlement or dismissal is unreasonable in light of existing evidence, that the Government has not fully investigated the allegations, or that the Government’s decision was based on arbitrary or improper considerations.’” *Id.* (quoting S. REP. NO. 99-345, at 26 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5291).

The Tenth Circuit adopted the standard articulated in *Sequoia Ridenour*, 397 F.3d at 936 (quoting *Sequoia*, 151 F.3d at 1145). It added that the test was not a difficult one, stating that the “rational relation” need not be a “tight fitting relationship.” *Id.* at 936-37. It is enough if there are “plausible, or arguable, reasons supporting the agency decision.” *Id.* at 937 (internal quotation marks omitted).

The District of Columbia Circuit rejected the *Sequoia* standard. It held that under § 3730(c)(2)(A), the government has an “unfettered right to dismiss [the] action.” *Swift*, 318 F.3d at 25. The court explained that it could “not see how § 3730(c)(2)(A) gives the judiciary general oversight of the Executive’s judgment in this regard. The section states that ‘The Government’—meaning the Executive Branch, not the Judicial—‘may dismiss the action,’ which at least suggests the absence of judicial constraint.” *Id.* (quoting § 3730(c)(2)(A)). The court concluded that the government’s decision to dismiss a *qui tam* action is virtually unreviewable by the court. *Id.* (citing *Heckler v. Chaney*, 470 U.S. 821, 831-33 (1985)).

We find that the reasoning of the Ninth and Tenth Circuits is more persuasive than that of the District of Columbia Circuit. The rational relationship standard accords with statutory interpretation and fosters transparency. It is consistent with the constitutional scheme of checks and balances.

Section 3730(c)(2)(A) mandates a hearing before a court may dismiss a *qui tam* action over a relator's objection. If the government's right to dismiss is "unfettered," as the District of Columbia Circuit has held, a hearing would be superfluous, rendering the requirement of a hearing a nullity. See *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632 (2018). Reducing the hearing requirement to insignificance violates a basic canon of statutory construction. *Corley v. United States*, 556 U.S. 303, 314 (2009) ("[O]ne of the most basic interpretive canons [is] that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant . . .'" (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004))); see also *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017) (discussing the "surplusage canon—the presumption that each word Congress uses is there for a reason.") (citing A. SCALIA & B. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 174-79 (2012)).

If the purpose of the hearing, as the District of Columbia Circuit read into the statute, is only to afford the relator an opportunity to convince the government to change its mind, what role does the judge play? Is the judge an observer, a mediator, or a participant in the debate? Certainly, if the government's right to dismiss is limitless, the judge is not an adjudicator. The judge has no decision to make if the government's right to dismiss is unchallengeable.

Requiring a hearing assures that the decision to dismiss is not arbitrary and without a valid governmental interest. The False Claims Act was created by Congress to enhance the government's ability to recover losses sustained as a result of fraud against the

government. S. REP. NO. 99-345, at 1 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5291.

The Legislative Branch has delegated to the Executive Branch the authority to pursue these actions with the relator. Requiring some justification, no matter how insubstantial, for a decision not to pursue a false claim, acts as a check against the Executive from absolving a fraudster on a whim or for some illegitimate reason. It prevents the Executive from abusing power.

The rational relationship test strikes a balance among the branches of government. It does not give unlimited power to the Executive to dismiss a legitimate action the Legislature created. Nor does it give the Judicial Branch unrestrained power to stop the Executive from acting to dismiss an action in the government's interest. Requiring the Executive to give a reason for a decision to dismiss a *qui tam* action the Legislature intended to be pursued is consistent with the notion of independent, co-equal branches of government.

In short, because the rational relationship test gives meaning to the requirement of a hearing and guards against arbitrary dismissal of an action intended by Congress, we conclude that it is the proper standard to be applied in analyzing a government motion to dismiss a *qui tam* action.

Here, under the *Sequoia* rational relationship test, the government has articulated a legitimate interest and dismissal will accomplish that interest. The government asserts it has a valid interest in avoiding litigation costs in a case that lacks sufficient factual and legal support.¹³ It has concluded, after extensive investigation, that the case is unlikely

¹³ Mot. to Dismiss at 14.

to yield a recovery justifying the costs and burdens it will incur if the case proceeds.¹⁴ The government, after having already expended substantial time and resources, has concluded that it is better to use its resources pursuing other claims.¹⁵

The government also maintains that the relators' allegations "conflict with important policy and enforcement prerogatives of the federal government's healthcare programs."¹⁶ It concluded that educational programs, informational support, medication instruction, and nurse access and support are not "remuneration" and are programs that are "appropriate and beneficial to the federal health programs and their beneficiaries."¹⁷

The government having satisfied the rational relationship test, the burden shifts to the relators to demonstrate that the dismissal is "fraudulent, arbitrary and capricious, or illegal." *Sequoia*, 151 F.3d at 1145. Relators do not contend that the government engaged in fraud or illegal action to dismiss the *qui tam* action for improper reasons. Indeed, there is no evidence that it did. They argue that the government's proffered reasons are arbitrary and unsubstantiated.¹⁸

Relators argue that the government did not do its "due diligence" in investigating the case to understand the merits.¹⁹ They contend that the government's concern

¹⁴ *Id.* at 14-16.

¹⁵ See *id.* at 15 n.8. The Department of Justice's Civil Division Fraud Section alone has spent over 1,500 hours on the actions brought by SMSPF's parent company, National Health Care Analysis Group. This figure does not include time spent by the United States Attorney's Office, the Department of Health and Human Services Office of Counsel to the Inspector General, law enforcement agents, investigators, or auditors.

¹⁶ *Id.* at 16.

¹⁷ *Id.* at 16-17 (citing 81 Fed. Reg. 8836801, 88396 (Dec. 7, 2016)).

¹⁸ Relators' Opp'n to Mot. to Dismiss at 12 (ECF No. 33).

¹⁹ *Id.* at 4, 11-13.

regarding discovery costs is not any different than any other *qui tam* action.²⁰ But, they argue, this case has the potential to return billions of taxpayer dollars to the government.²¹ In response to the public policy rationale, the relators contend that the free services the defendants provided were not “benevolent acts” to help patients, but rather inducements to physicians to prescribe Rebif.²² They claim the real reason for the government’s moving to dismiss is its dislike of the corporate relator as a “professional relator.”²³

The relators have failed to show that the government’s decision is arbitrary and capricious. The government has invested significant time and resources investigating the relators’ claims over a lengthy period of time. Eight United States Attorneys’ Offices have concluded that the allegations in each of the cases lack sufficient factual and legal support to justify the cost of the litigation and that the allegations in this case conflict with public policy interests.²⁴

The government’s investigation included: (1) assembling a team consisting of Department of Justice attorneys; law enforcement agents from the Office of Personnel Management – Office of the Inspector General, Department of Health and Human Services – Office of the Inspector General, the Defense Department Criminal Investigation Service, and the FBI; and subject matter experts from the Office of Counsel to the Inspector General at the Department of Health and Human services; (2) reviewing the Department of Health and Human Services – Office of the Inspector General’s

²⁰ *Id.* at 13.

²¹ *Id.*

²² *Id.*

²³ *Id.* at 20-22.

²⁴ Reply at 1-2.

guidance on common industry practices; (3) reviewing the information provided in the complaint, amended complaint, second amended complaint, and disclosure materials; (4) interviewing witnesses; (5) collecting documents and information; (6) meetings at Pfizer and Serono; (7) reviewing documents from Pfizer and Serono; (8) meetings with Pfizer and Serono's counsel; (9) meetings and communications with relators' counsel; and (10) reviewing supplemental information provided by the relators.²⁵

The investigation spanned 18 months. The government stated that it collected "quite a bit of information" on each of the different theories of liability in the case, ultimately concluding that there was insufficient legal and factual support to pursue this action.²⁶ We are satisfied that the government has fully investigated the claim.

Conserving costs and promoting educational services are rationally related to accomplishing legitimate governmental interests in redirecting money and resources to other claims while benefiting the government's healthcare programs and their recipients. These are legitimate governmental interests. See *Ridenour*, 397 F.3d at 936 (quoting *Sequoia*, 151 F.3d at 1145) ("rational relation" need not be "tight fitting relationship" and is established with "plausible, or arguable, reasons supporting the agency decision."). Like any other plaintiff in a civil case, the government has the option to end litigation it determines is too expensive or not beneficial.

Preserving litigation costs is a valid interest even where the claims may have merit. See *Sequoia*, 151 F.3d at 1146 ("government can legitimately consider the burden imposed on the taxpayers by its litigation, and that, even if the relators were to litigate the

²⁵ Mot. to Dismiss Hearing Tr. at 38-41.

²⁶ *Id.* at 41.

FCA claims, the government would continue to incur enormous internal staff costs.”); *Swift*, 318 F.3d at 254 (“the government’s goal of minimizing its expenses is still a legitimate objective, and dismissal of the suit furthered that objective.”). The government’s rational reasons for dismissing under § 3730(c)(2)(A) may be sufficient to overcome the potential merit of a *qui tam* action. *Sequoia*, 151 F.3d at 1143-44 (even “a meritorious suit may be dismissed upon a proper showing [by the government].”); *Ridenour*, 397 F.3d at 930 (dismissal warranted even when government conceded relators’ suits were meritorious). The decision to dismiss this case is rationally related to the valid governmental purpose of preserving resources for other litigation and protecting the government’s healthcare programs. See *Heckler*, 470 U.S. at 831; *Selective Serv. Sys. v. Minn. Pub. Interest Research Grp.*, 468 U.S. 841, 859 n.17 (1984).

The reasons given by the government are not a cover for an illegitimate reason and do not mask an animus toward the corporate relator. They are concerns that any party to litigation may have when deciding whether to continue pursuing a case. The government is entitled to do a cost / benefit analysis to decide whether to pursue a case, even a meritorious one.

Conclusion

The government has the authority to dismiss this action brought on its behalf pursuant to 31 U.S.C. § 3730(c)(2)(A). It has provided valid reasons for dismissal and has adequately demonstrated that dismissal is rationally related to accomplishing its interests. Relators have not presented a colorable claim that dismissal would be unreasonable, arbitrary, or an abuse of discretion. Therefore, we shall grant the government’s motion and dismiss this action.